

REMARKS

A. Status of the Claims

Claims 1-32 are currently pending and presented for reconsideration.

B. Status of the Specification

The Specification has been amended to recite the ATCC deposit information for soybean lines 0007583, 0008079, and 0137335. No new matter has been added.

C. Claim Rejection Under 35 U.S.C. § 112, First Paragraph – Written Description

The Action maintains the rejection of claims 1-32 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, it is asserted that the specification fails to provide an adequate description of the genus of soybean plants that are agronomically elite and have a mean whole seed total protein content between 45-50%, a mean whole seed total protein plus oil content of between 64-70%, a mean whole seed total oil content of at least 20%, and a commercially significant yield, as well as parts thereof and methods of use, in terms of their genetic, morphological, and/or physiological characteristics.

Applicants previously noted that claim 1 was amended to recite soybean variety SN30003 as a parent plant. Each of claim 1-29 incorporates this element by dependency on claim 1, or otherwise specify method steps involving use of variety SN30003 as a parent plant. These claims specify soybean plants demonstrating (1) agronomically elite characteristics; (2) mean whole seed total protein content of between 45-50%; (3) mean whole seed total protein plus oil content of between 64-70%; (4) mean whole seed total oil content of at least 20%; (5) commercially significant yield; and (6) wherein the plants are progeny of SN30003 or of a subsequent generation of such a plant.

Applicants submit that this subject matter is fully described in the Specification in compliance with § 112, first paragraph. In particular, Applicants respectfully reiterate that the

Specification explicitly provides multiple examples demonstrating that the Applicants were in possession of this subject matter at the time of filing. For instance as noted previously, in Example 1 soybean variety 0007583 is shown to have been derived from a cross with variety SN30003, and selected based on the criteria listed above, including seed yield, lodging resistance, emergence, seedling vigor, disease tolerance, maturity, plant height, and seed oil and protein content, among others (Specification, page 44, lines 5-7; page 45, lines 2-4; page 49, lines 18-20). Likewise, as shown in Example 5, soybean variety 0137441 is derived from a cross with variety SN30003, and selected based on agronomic characteristics including yield, lodging resistance, emergence, seedling vigor, disease tolerance, maturity, plant height, and seed oil and protein content (Specification, page 57, lines 6-19). Seed of soybean line 0007583 has been deposited under ATCC Accession No. PTA-5764. The Specification has been amended to indicate this. At least these two lines *prima facie* demonstrate possession of the claimed subject matter by the Applicants. The written description requirement has, therefore, been fully complied with. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph).

M.P.E.P. 2163 explicitly states that "...Possession may be shown in a variety of ways...An application specification may show actual reduction to practice...in the case of biological materials, by specifically describing a deposit made in accordance with 37 CFR 1.801..." Applicants further note that the Action does not dispute or find unclear any of the claim terms, for instance in claim 1 or in method claims 16 or 30. Possession has been shown by both actual reduction to practice and by a seed deposit. Thus, one of skill in the art upon reading the Specification and claims, and understanding that plants grown from seed of ATCC Accession

No. PTA-5764 produce seed with the claimed characteristics, could “reasonably conclude that the inventor had possession of the claimed invention” [M.P.E.P. 2163 I]. In view of this, and based on the working examples and knowledge of one of skill in the art of plant breeding, one of skill in the art could also generate new varieties displaying the claimed characteristics using the same protocols described therein, using SN30003 or a line derived therefrom as a parent plant.

Additionally, Applicants respectfully note that the Examiner “has the initial burden...of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims.” [M.P.E.P. 2163 II (A)]. Neither this Action nor the previous Actions provide clear evidence why a person skilled in the art of plant breeding would not recognize that the written description of the invention provides support for the claims. Applicants respectfully submit that, by repeatedly asserting that lines 0007583 and others are described, this Action actually provides clear evidence why one of skill in the art would indeed recognize that the inventors had possession of the claimed subject matter (*e.g.* the claimed soybean plants, plant parts, and/or seeds, and methods for producing these) at the time of filing of the application.

Given that multiple examples of soybean lines displaying the claimed characteristics are described in the Specification, and that seed of line 0007583 (*i.e.* a product of the claimed method) has been deposited in accordance with 37 CFR 1.801, it is further entirely unclear how else the claimed products or methods might be described so as to satisfy the Examiner’s apparent standard for meeting the Written Description requirement. Although the Action apparently implies that the claimed invention is not susceptible to description, it provides neither any evidence nor any reasoning for this assertion. As well, the meaning of no claim terms is being disputed by the Examiner. Applicants respectfully submit that the initial burden on the Examiner

to present evidence why a person skilled in the art would not recognize that the written description of the invention provides support for the claims still has not been met, especially in view of MPEP 2163.04, which states that

The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). A description as filed is ***presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption.*** See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97. (emphasis added).

In the absence of any such showing, Applicants respectfully request withdrawal of the rejection.

Further, even if, only *in arguendo* and not accepted by the Applicants, it is assumed as asserted by the Action that the Specification only satisfies the written description requirement for lines 007583 and 0137441, among others, Applicants respectfully submit that this written description rejection is not properly applied to both the claims relating to soybean plants derived from line SN30003, and to the claimed methods for breeding soybean plants. Applicants note that the Action provides no reasoning why the recited steps of method claims 16-28 and 30-31 are not clearly described for one of skill in the art of plant breeding. For instance, claim 30 is an independent method claim which recites use of line SN30003 as a parent plant, and none of the recited steps of this claim have been asserted to be unclear. Rather, as acknowledged by the Action, multiple lines are described that clearly indicate that the method has successfully achieved the claimed result. Thus, at least these method claims meet any objective standard for written description as understood from the perspective of one of skill in the art of plant breeding.

Withdrawal of the rejection on this basis at least of claims 16-28 and 30-31, in view of 35 USC § 112, first paragraph- written description, is thus respectfully requested.

Applicants also note that the rejection pertaining to claims 30-32 has been maintained, apparently because it is unclear what are the conditions of deposit as stated in the Specification at page 41, 7th paragraph. Applicants note again that no aspect of this Action or the previous Actions indicate how this rejection should properly apply to these method claims. The Action acknowledges that such soybean varieties were in fact identified, and Applicants submit that this is *prima facie* evidence that the methods used to obtain them, which are described in the Specification, must have been in the possession of the inventors. That is, the detailed description and working examples fully support the claimed methods. Applicants again submit that, for instance, line 0007583 has been deposited at accession number PTA-5764, as noted above. Further, the Specification has been amended herein to indicate this. It is thus respectfully requested that this rejection of claims 30-31 as outlined in the Action at page 5, 2nd to last paragraph, to page 6, 1st paragraph, also be withdrawn.

Likewise regarding the subject matter of product-by-process claim 32, which depends from claim 30 and describes a resulting plant for instance as grown from ATCC accession PTA-5764, such a plant may clearly be recognized by one of skill in the art, for instance by testing mean whole seed oil content, mean whole seed protein content, mean whole seed protein plus oil content, and yield. Thus, this claim must also satisfy the Written Description requirement, further in view of the availability of ATCC Accession No. PTA-5764, and in that no claim terms are asserted to be unclear. Withdrawal of this rejection of product-by-process claim 32 is thus also respectfully requested .

D. Claim Rejection Under 35 U.S.C. § 112, First Paragraph- Enablement

The Action rejects claims 1-29 and 32 under 35 U.S.C. § 112 based on the assertion that the specification does not reasonably provide enablement for each and every progeny soybean plant of SN30003 having the claimed mean whole seed protein content, whole seed oil content, and mean whole seed total protein plus oil content, and a commercially significant yield. Applicants note that method claims 30-31 are not included in this enablement rejection.

In response, Applicants note that the Specification provides sufficient disclosure to satisfy the enablement requirement of 35 U.S.C. § 112, First Paragraph, for this subject matter, in that the Specification provides working examples within the scope of the claims, and the teachings of the Specification combined with the knowledge of one of ordinary skill in the art provides sufficient guidance to practice the invention, both with respect to the product claims and the method claims. Indeed, the assertion of the Action, that the Specification provides enablement for soybean varieties 0007583 and 0137441, among others, actually argues that the claims are enabled, since products of the claimed methods were in the possession of the inventors, and no steps of these method claims are asserted to be unclear in the Action.

For instance, as noted previously, in Examples 1 and 5, soybean varieties 0007583 and 0137441 are identified, derived from initial crosses of varieties A2553xSN30003, and AG3302xSN30003, respectively, and selected based on agronomically elite criteria including seed yield, lodging resistance, emergence, seedling vigor, disease tolerance, maturity plant height, and seed oil and protein content, among others (*e.g.* Specification, page 44, lines 5-7; page 49, lines 18-20; page 45, lines 2-4; also Specification, page 57, lines 17-19). Variety 0007583 is further described as possessing a protein content of 46.2% (Tables 2, 7), and an oil content of 20.4% (*e.g.* Table 2, Table 7, leading to an oil + protein content of 66.6%. Yield of 007583 is reported as 54.7 bu/ac in Table 7, and yield of 00137441 is reported as 45.2 bu/ac in

Table 24. Variety 0137441 is further described as possessing a protein content of 45.4% and an oil content of 20.4%, leading to an oil + protein content of 65.8% (Table 24 at page 59). Again, whether one skilled in the art could re-produce these (same) varieties using the same parents and the same selection techniques is not relevant to the enablement of the claimed invention, since the claims do not relate to producing identical varieties. Instead, the claims relate to producing additional varieties displaying the claimed characteristics.

Finally, the Action continues to assert a lack of enablement (*e.g.* Action, page 6, second from last paragraph) without any further reasoning or support. Referring back to pages 5-7 of the previous Action of January 9, 2007 as noted at page 6, section 10 of the present Action, Applicants note that the Applicants' arguments against those previously asserted reasons for a lack of enablement have each been found persuasive in this action (present Action; last paragraph of present Action on page 6, through third full paragraph of page 7).

In view of the foregoing, withdrawal of the rejection is respectfully requested.

E. Claim Rejection Under 35 U.S.C. § 103(a)

The Action maintains the rejection of claims 15 and 30-32 under 35 U.S.C. § 103(a) as being unpatentable over Wilcox (*Crop Sci.* 38:900, 1998), in view of Conway (U.S. Patent No. 6,140,556). Applicants respectfully traverse.

The Action alleges that SN30003 could be crossed with another soybean cultivar to produce novel soybean cultivars, by one of skill in the art. Applicants do not dispute this. However, the issue is whether any such resulting novel soybean cultivars would have, or would have been expected to have, at the filing date of the present application, the claimed characteristics (*i.e.* simultaneous oil content, protein content, protein plus oil content, yield, and other elite agronomic characteristics. Although SN30003 might be used in a cross with a second

variety that displays 20% seed oil content, a skilled soybean breeder simply would have had no expectation of success, *i.e.* that any resulting progeny plant line would simultaneously display the claimed characteristics, such as the claimed simultaneous levels of seed oil content, seed protein content, and seed oil plus seed protein content. This was discussed in the previous response, for instance where the strong negative correlation between seed oil content and seed protein content, was described. The action does not address this, instead maintaining the rejection without reasoning or support, and only stating that novel cultivars might be produced, without explaining how such novel cultivars might have been expected to demonstrate the claimed characteristics.

On the contrary, the art very clearly teaches away from the claimed result. The cited reference by Wilcox does not describe characteristics of progeny plants. Instead, it only states that the lines of Wilcox might be useful in further breeding attempts that could “minimize” reductions in oil content without describing any actual resulting oil content, or oil plus protein content. This implicitly recognizes the difficulties in breeding for characteristics such as those presently claimed, does not indicate that the claimed characteristics would have been achievable prior to the teachings of the present application, and indeed teaches away from achieving the claimed levels of oil, protein, and oil plus protein content. Again, that simultaneous maintenance of protein, oil, and yield at the claimed levels in progeny lines was not known to be achievable. Applicants respectfully request that the Examiner point out any teachings in the art that would lead one of skill, as of the filing date, to conclude that such novel cultivars derived from a cross using SN30003 as a parent would display these claimed characteristics. In the absence of such a showing withdrawal of the rejection is respectfully requested.

F. Claim Rejection Under 35 U.S.C. § 102(b) or Alternatively 35 U.S.C. § 103(a)

The Action rejects claims 1-32 under 35 U.S.C. § 102(b) or alternatively under 35 U.S.C. § 103(a) as obvious over Cober *et al.* (*Crop Sci.* 40:39-42, 2000). Applicants respectfully traverse.

The Action asserts that Cober describes soybean plants having whole seed total protein content between 45% and 50%, total protein plus oil content of between 64% and 70%, and a commercially significant yield. The Action also asserts that Cober *et al.* disclose soybean plants having whole seed total oil content of at least 20% (asserted to be shown at page 41, for instance in Fig. 3). Applicants respond that Fig. 3 of Cober does not indicate that any lines simultaneously displaying, for instance, 20% seed oil content, while also displaying the claimed protein and protein plus oil content. Fig. 3 simply does not provide this information because it does not identify any individual lines, nor does it correlate the seed protein and seed oil content of any individual line such that a meaningful comparison with a line as presently claimed may be made. Thus, Applicants disagree with the Action's assertion that, in view of Cober, the soybean plant taught by the prior art "differs from the claimed soybean plant only in its method of making" [Action, page 9, last paragraph]. On the contrary, Cober does not describe a soybean plant as claimed, and the claimed plants are distinct from any in the prior art. Given this, the citation of *In re Thorpe* is not apt. Thus both the product claims and the product-by-process claims relate to subject matter that is novel, and withdrawal of the rejection is respectfully requested.

Applicants also note regarding the method claims, that the Action, at page 9, 4th paragraph, appears to acknowledge that the method used for making the claimed plants is novel, *i.e.* differs from the prior art. Withdrawal of the rejection at least of the method claims is respectfully requested in view of this.

G. New Claim Rejections Under 35 U.S.C. § 103(a)

The Action rejects claims 1-14 and 16-29 as obvious over Wilcox (*Crop Sci.* 38:900, 1998) in view of Conway (U.S. Patent 6,140,556). Applicants respectfully traverse.

Applicants respectfully draw the Examiner's attention to section E above, which related to a similar rejection, using the same references, but of claims 15 and 30-32. Applicants note that the Action acknowledges that Wilcox (1998) does not describe soybean line C1944 as displaying at least 20% oil content. Although the Action asserts (paragraph bridging pages 11-12 of Action) that one of ordinary skill in the art could have used a plant displaying at least 20% seed oil content as the other parent in a cross, Applicants again note, as also detailed above, that there would have been no expectation that progeny of such a cross, in any subsequent generation, would have displayed the claimed characteristics, in particular the simultaneous claimed levels of seed oil, seed protein, and seed protein plus seed oil. Wilcox in view of Conway is at best an invitation to experiment further, but with no expectation of success.

On the contrary, because of the known strong negative correlation between seed oil content and seed protein content which further teaches away from a breeder being able to achieve the claimed result, a skilled worker would not have expected that the claimed oil and protein levels could be achieved in a progeny plant. Rather, as indicated by Wilcox's teaching that C1944 was thought to be useful for minimizing reductions in oil content (when breeding with high protein lines), the seed oil and protein levels of the parent plants were not expected to be maintained at the levels of one or the other in a given parent plant, or at the claimed levels.

Finally, the Applicants respectfully submit that the assertion that one of ordinary skill in the art would have had a reasonable expectation of success is mistaken and is not supported by the cited art, because "increasing seed protein while minimizing reductions in seed oil content" is not at all equivalent to achieving the claimed seed oil, protein, and protein plus oil levels. The

claimed subject matter is thus unexpected in view of the prior art. Withdrawal of the rejection is respectfully requested.

H. Conclusion

In view of the above, it is submitted that the rejections to the claims have been overcome, and the case is in condition for allowance.

The Examiner is invited to contact the undersigned agent at (214) 259-0932 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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